



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|------------------------------|------------------|
| 10/565,349 | 01/20/2006 | Alexandr Chernyshov | 11876-23US JP/mp (06-117) | 2093 |
| 34704 7590 10/28/2008 BACHMAN & LAPOINTE, P.C. 900 CHAPEL STREET SUITE 1201 NEW HAVEN, CT 06510 | | | | |
| EXAMINER ZIMMERMAN, JOHN J | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1794 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 10/28/2008 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/565,349

Applicant(s)

CHERNYSHOV ET AL.

Examiner

John J. Zimmerman

Art Unit

1794

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/20/2006 (preliminary amendment).
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-12 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 1/20/2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 20060120
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

FIRST OFFICE ACTION

Preliminary Amendment

1. This First Office Action considers the claims as presented in the correspondence titled "PRELIMINARY AMENDMENT" received January 20, 2006. Claims 1-12 are pending in this application.

Information Disclosure Statement

2. The information disclosure statement received January 20, 2006 has been considered. An initialed form PTO-1449 is enclosed with this First Office Action.

Specification

3. The abstract of the disclosure is objected to because the abstract of the disclosure does not commence on a separate sheet apart from any other text. A new abstract on a separate sheet free of extraneous text is required.

Claim Objections

4. Claim 11 is objected to because of the following informalities: Proper Markush language is "selected from the group consisting of" (e.g. line 2 of claim 11). Appropriate correction is required.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 10-11 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112, Second Paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
9. Claims 10-11 provide for the use of the material, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is

intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

10. Claim 1 is indefinite since it is not clear if the material in parentheses in line 2 is required or merely suggestive. The dependent claims are rejected since they incorporate the indefinite matter of claim 1. Likewise, claim 12 is indefinite since it is not clear if the material in parentheses in line 4 is required or merely suggestive. It is unclear what "mechanical properties" are "suitable for surgical implantation" and what are not suitable for surgical implantation (e.g. claim 1, lines 17-19).

Claim Rejections - 35 USC § 112, First Paragraph

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. While the specification discusses articles which exhibit the limitations of the pending claims, the specification fails to adequately teach one of ordinary skill in the art to manufacture articles that exhibit the limitations of the pending claims. Merely describing the end product of applicant's invention does not necessarily satisfy the requirement that applicant adequately disclose methods of making said end product.

A careful review of the applicant's specification fails to find adequate teaching for one of ordinary skill in the art at the time the invention was made to manufacture the claimed invention. It is unclear where the specification teaches how to vary the oxygen concentration of a matrix of TiNi with interconnected struts (e.g. claim 1, line 6). It is unclear where the specification teaches how to adjust the oxygen concentration of the secondary phases within the claimed ranges (e.g. claims 3-5). The specification merely states that the oxygen content can be achieved by "air scavenging, purging the reactor mould with inert gas and raw material selection" (e.g. page 10, lines 3-8). These are only broad generalized suggestions and are not adequate descriptions for teaching one of ordinary skill in the art to meet the oxygen content limitations of the matrix and/or the secondary phases in the pending claims. The generalized suggestions in the specification do not contain adequate teachings of how to perform the suggested operations and how to control said operations to meet the conditions of the pending claims for either or both of the matrix and the secondary phases. In addition, the specification fails to teach one of ordinary skill in the art how to form the precipitates interspersed within the matrix (e.g. claim 1, line 9), how to limit their volume (e.g. claim 7) and how to vary the Ti content of the secondary phases to meet the atomic ratio limitations of the pending claims (e.g. see claims 3-5). In addition, the specification fails to disclose how to obtain a "spheroid configuration" in a Ti-enriched secondary phase (e.g. claim 6). The specification also fails to adequately disclose how to obtain mechanical properties of the matrix having and elastic modulus, elastic deformation, ultimate strength, strain to failure and yield strength meeting the conditions of claim 9. No particular processing steps or processing conditions are disclosed in the specification that lead to the claimed properties.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additional prior art made of record serves to further establish the level of ordinary skill in the art. None of the references of record disclose or make obvious the specific combination of limitations required by independent claim 1 and therefore no art-based rejections have been made in this First Office Action. To overcome the rejections based on a non-enabling disclosure, applicant are encouraged to submit evidence (e.g. patents, publications, etc. . .) to establish enablement.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John J. Zimmerman whose telephone number is (571) 272-1547. The examiner can normally be reached on 8:30am-5:00pm, M-F. Supervisor Rena Dye can be reached on (571) 272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

John J. Zimmerman
Primary Examiner
Art Unit 1794

/John J. Zimmerman/
Primary Examiner, Art Unit 1794

jjz
October 26, 2008